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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,041	01/23/2004	Gregory T. A. Kovacs	612,404-435	7951
34263	7590	06/29/2005	EXAMINER	
O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618			SODERQUIST, ARLEN	
			ART UNIT	PAPER NUMBER

1743

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,041

Applicant(s)

KOVACS, GREGORY T. A.

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1-23-04, 7-19-04</u> | 6) <input type="checkbox"/> Other: ____ |

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1. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 and 14 it is not clear if the memory associated with each electrode is also disposed on the support or can be located of the support and connected thereto to provide the association. For examination purposes the broader scope will be used since there is no positive limitation to have the memory also disposed on the support. Additionally in claim 14, it is not clear what steps are required to "selectively" address or apply electrical current or voltages to the electrodes as set forth in the claim preamble. The providing step simply provides the structure, but fails to set forth positive steps to accomplish the intent of the preamble.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller (WO 95/12808). In the published application Heller teaches programmable electronic devices for molecular biological analysis and diagnostics that are substantially similar to the instant claims. A self-addressable, self-assembling microelectronic device is designed and fabricated to actively carry out and control multi-step and multiplex molecular biological reactions in microscopic formats. These reactions include nucleic acid hybridization, antibody/antigen reaction, diagnostics, and biopolymer synthesis. The device can be fabricated using both microlithographic and micromachining techniques. The device can electronically control the transport and attachment of specific binding entities to specific micro-locations. The specific binding entities include molecular biological molecules such as nucleic acids and polypeptides. The device can subsequently control the transport and reaction of analytes or reactants at the addressed specific microlocations. The device is able to concentrate analytes and reactants, remove non-specifically bound molecules, provide stringency control for DNA hybridization reactions, and improve the detection of analytes. The device can be electronically replicated. In a first aspect of the invention, a device with an array of electronically self-addressable microscopic locations. Each microscopic location contains an underlying working direct current

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(DC) micro-electrode supported by a substrate. The surface of each micro-location has a permeation layer for the free transport of small counter-ions, and an attachment layer for the covalent coupling of specific binding entities. A specific binding entity is generally meant to be a biological or synthetic molecule that has specific affinity to another molecule, through covalent bonding or non-covalent bonding. Preferably, a specific binding entity contains a functional chemical group (primary amine, sulfhydryl, aldehyde, etc.), a common sequence (nucleic acids), an epitope (antibodies), a hapten, or a ligand, that allows it to covalently react or non-covalently bind to a common functional group on the surface of a micro-location. Specific binding entities include, but are not limited to: deoxyribonucleic acids (DNA), ribonucleic acids (RNA), synthetic oligonucleotides, antibodies, proteins, peptides, lectins, modified polysaccharides, synthetic composite macromolecules, functionalized nanostructures, synthetic polymers, modified/blocked nucleotides/nucleosides, modified/blocked amino acids, fluorophores, chromophores, ligands, chelates and haptens. The invention also features methods for detecting and analyzing reactions that have occurred at the addressed micro-locations using self-addressed microelectronic devices with associated optical, optoelectronic or electronic detection systems or self-addressed microelectronic devices with integrated optical, optoelectronic or electronic detection systems. Page 34, line 34 to page 35 line 19 teaches that the ability to provide electronic stringency control to hybridizations also provides mechanisms for detecting DNA hybridization without reporter group labeled DNA probe. It provides a way to carry out a more direct detection of the hybridization process itself. A fluorescent dye detection process is shown in figures 12a through 12d and described in Examples 4 and 6. Direct detection of DNA hybrids can be achieved by using DNA binding dyes such as ethidium bromide. The dye binds to both double-stranded and single-stranded DNA but with a greater affinity for the former. In figure 12b positively charged dye (122) is transported to negatively biased micro-locations. The dye binds to both hybridized (120) and unhybridized (121) DNA sequences (figure 12c). By biasing the micro-locations positive and delivering a defined amount of power in a given amount of time, the dye molecules bound to unhybridized micro-locations is selectively removed. The amount of power applied does not adversely affect the DNA hybrids. The hybridized DNAs with associated dye molecules *are then fluorescently detected* using associated or *integrated optical systems*. Page 33, lines 17-26 teach various forms of the detection devices including an imaging

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detector element (CCD, ICCD, Microchannel Plate) or photon counting PMT system. One alternative is to associate a sensitive CCD detector or avalanche photodiode (APD) detector directly with the device in a sandwich arrangement. Another alternative is to integrate optoelectronic or microelectronics detection in the device. Figure 5 and the associated discussion of pages 25-26 teach the device controlled by a multiplex switch controller (56) and a DC power supply (associated memory and source of electrical current or voltage). Examples 7-8 teach this configuration used to maintain each individually addressable microlocation at different potentials during use of the device.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 10-11, 13-14 and 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 5,965,452 and claims 1-24 of US Patent 6,258,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are of a scope that totally encompasses the patented claims or interchange use a notoriously well known form (amplifier or sample-and-hold) of a generic term (driving element or memory, respectively).

6. Claims 1-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,682,936 and claims 1-28 of US Patent 6,867,048. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the instant claims are of a scope that totally encompasses the patented claims or interchange use a notoriously well known form (amplifier or sample-and-hold) of a generic term (driving element or memory, respectively).

7. Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 11/081123. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are of a scope that totally encompasses the patented claims or interchange use a notoriously well known form (amplifier or sample-and-hold) of a generic term (driving element or memory, respectively).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art was cited in the parent applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Arlen Soderquist

ARLEN SODERQUIST
PRIMARY EXAMINER